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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,401	11/21/2005	Hiroshi Tsuchita	Q88294	1465
65565 7590 07/20/2007 SUGHRUE-265550 2100 PENNSYLVANIA AVE. NW WASHINGTON, DC 20037-3213			EXAMINER TSAY, MARSHA M	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 07/20/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/537,401	<b>Applicant(s)</b> TSUCHITA ET AL.	
	<b>Examiner</b> Marsha M. Tsay	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1656

This Office action is in response to Applicants' remarks received April 27, 2007. Claims 14-15 are canceled. Claims 1-13, 16-23 are currently under examination.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Priority: The priority date is December 2, 2003.

### **Objections and Rejections**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-13, 17-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Brantman (US 4687782; IDS). Brantman teaches diet supplements comprising a combination of amino acids, i.e. branched amino acids, to promote muscle adaptation to strenuous exercise. In example 1, Brantman teaches a composition comprising leucine, isoleucine, valine, glutamine, and a whey protein, i.e. casein, soy protein, lactalbumin (col. 5 lines 60-65; claims 2-4, 7-10, 13, 18-19). Brantman further teaches a method of supplementing the diet of an athlete by having the athlete drink a solution comprising leucine, isoleucine, valine, glutamine, and a whey protein; and having the athlete drink the solution (col. 6 lines 42-53; claims 17). In col. 4 lines 45-50, Brantman also teaches numerical ranges for the amino acids used in the composition: leucine

Art Unit: 1656

(20-45 parts), isoleucine (15-40 parts), valine (15-40 parts), glutamine (10-30 parts) (claims 5-6, 11-12, 20-23), wherein the relative proportions of the amino acids are preferably within 20% of the recited ranges (col. 5 lines 20-25).

Applicants have currently amended claim 2 to recite a composition for a sustained improver of muscular fatigue, which consists essentially of leucine, isoleucine, valine, glutamine and a whey protein component. In their remarks, Applicants assert the Brantman reference is relied upon to teach diet supplements comprising an amino acid mixture. The amino acid mixture taught by Brantman consists essentially of carnitine, leucine, isoleucine, valine, glutamine, valine, and water. Applicants assert that the composition taught by Brantman contains carnitine as an essential ingredient. By contrast, instant claims 2 and 8 have been amended to each recite that the claimed composition/food or drink “consists essentially of” leucine, isoleucine, valine, glutamine, and a whey protein component. Applicants’ arguments have been fully considered but they are not persuasive.

The use of open language “consists essentially of” to describe compositions allows room for unspecified components as long as they do not materially affect the basic and novel characteristics of the claimed invention. As noted above, Brantman teaches diet supplements comprising a combination of amino acids, i.e. branched amino acids, to promote muscle adaptation to strenuous exercise. Therefore, Brantman teaches a composition for improving muscle fatigue that comprises carnitine, glutamine, isoleucine, leucine, valine, and a whey protein (col. 8 lines 5-18). While the composition of Brantman does include the additional component of carnitine, the carnitine does not materially affect the basic and novel

Art Unit: 1656

characteristics of the claimed invention because both compositions consist essentially of branched amino acids and a whey protein and are used/administered to improve muscle fatigue and promote muscle adaptation, i.e. during strenuous exercise. Therefore, the rejection of the instant claims under 35 U.S.C. 102(b) is maintained under Brantman.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantman (US 4687782; IDS). The teachings of Brantman are outlined above. Brantman further teaches a composition comprising: an amino acid mixture consisting essentially of carnitine, isoleucine, leucine, valine, glutamine, and a whey protein, i.e. casein, soy protein, lactalbumin (col. 7 lines 30-50), adapted for use with water as a diet supplement for facilitating the adaptation of skeletal muscle and liver to a program of strenuous exercise. Brantman does not specifically teach a composition consisting of leucine, isoleucine, valine, glutamine, and a whey protein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Brantman and formulate a composition consisting of isoleucine, leucine, valine, glutamine, and a whey protein, i.e. casein (claim 1) and administer it to an athlete (claim 16). One of ordinary skill would be motivated to administer said composition to an athlete and expect it to be successful in improving fatigue during exercise because Brantman teaches a composition consisting essentially of the branched amino acids, i.e.

Art Unit: 1656

isoleucine, leucine, leucine, valine, glutamine, and a whey protein, which can be administered to promote muscle adaptation to strenuous exercise in a person.

In their remarks, Applicants assert the composition taught by Brantman consists essentially of carnitine, leucine, isoleucine, valine, glutamine, valine, and water. Applicants assert that the composition taught by Brantman contains carnitine as an essential ingredient. Applicants' arguments have been fully considered but they are not persuasive.

Brantman teaches a composition that improves muscle during exercise, wherein the composition consists essentially of 0.025 g carnitine, 0.5 g glutamine, 0.625 isoleucine, 0.85 g leucine, 0.625 valine, and 2.5 g whey protein (col. 8 lines 5-18). Out of all the branched amino acids present in the Brantman composition, the amount of carnitine present (0.025 g) is the least compared with the other components, i.e. 0.5 g glutamine, 0.625 isoleucine, 0.85 g leucine, 0.625 valine, and 2.5 g whey protein. Therefore, even if carnitine is disclosed as an ingredient in the composition of Brantman, it does not appear that its absence would interfere with the basic and novel characteristics of the claimed invention, i.e. which is to improve muscle fatigue and/or promote muscle adaptation to strenuous exercise. As disclosed by Brantman, it appears that carnitine helps to minimize the effects of ammonia that is generated during catabolism of amino acids, i.e. which occurs during strenuous exercise (col. 3 lines 64-68). Therefore, one of ordinary skill would recognize that a composition consisting of glutamine, isoleucine, leucine, valine, and whey protein alone is sufficient to provide therapeutic benefit, i.e. providing the branched amino acids that are necessary for stimulating protein synthesis in skeletal muscle and in liver in order to improve muscle fatigue (col. 3 lines 20-35, col. 4 lines 15-20). For these

Art Unit: 1656

reasons, the rejection of the instant claims under 35 U.S.C. 103(a) as being unpatentable over Brantman is maintained.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1656

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 16, 2007

*re. Monshi*  
**MARYAM MONSHIPOURI, PH.D.**  
**PRIMARY EXAMINER**